



## Are DIY Aligners causing more harm than cure?

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### ABSTRACT

**INTRODUCTION:** Over last 30 years revolutionary changes have occurred in the field of orthodontics (associated with treatment of malaligned teeth and abnormal facial growth). One such breakthrough development is clear aligner treatment, that provides superior aesthetics, especially during the treatment. But commercialization of this technique has given rise to a newer concept of DIY (do-it-yourself) aligners.

**METHODOLOGY:** A questionnaire study was prepared and presented to the dental professionals of Maharashtra, India. Their responses were recorded and analysed to study their knowledge, approach, attitude and practice related to DIY Aligners. Cronbach alpha value was calculated to be 0.77, that validated the questionnaire. Statistical analysis was done using descriptive analysis.

**RESULTS:** A total of 301 individuals participated in the study, 77.4% believe that the major cause for failure of DIY Aligners is lack of orthodontic guidance.

**CONCLUSION:** The treatment provided should grant the patient maximum care and high-grade quality service and hence it is required to educate potential patients on the value of pursuing treatment with highly qualified orthodontic specialists.

**KEYWORDS:** Do-it-yourself, orthodontics, aligner, multinational corporations.

### I. INTRODUCTION:

Orthodontics is a specialized branch of dentistry which deals with the treatment of malocclusion and abnormal facial skeletal growth. Over the last 30 years, there have been

revolutionary changes in this field due to advancements in diagnostics and scanning techniques. One such breakthrough development is the invention of clear aligners (1997). Clear aligners are transparent trays made of PVC (Polyvinylchloride) used to straighten teeth. Their main advantage is superior aesthetics, removable nature and virtual invisibility.

Over the last few years, many multinational corporations (MNC'S) have taken over the sale and marketing of clear aligners and have come up with the concept of 'Do-it yourself' (DIY) Aligners. DIY Aligners are constructed and provided without person-to-person contact between the patient / client and without an orthodontist's consultation during aligner treatment (1). Social media platforms are being used by MNC'S to provide the consumers with home orthodontic treatment via aligners without having to visit a dental clinic. False publicity regarding the benefits of using aligners directly, without the intervention of an orthodontist's consult, is causing harm to the patient (1). The main disadvantage of DIY Aligners, is the lack of regular follow-ups that traditional (braces treatment) orthodontic treatment offers (2). 'One-to-one' contact with an orthodontist helps the patient to easily get in touch with the doctor when needed. A factor causing relapse of treatment with DIY Aligners is that not all malaligned teeth can be corrected with them (1), (2). Here the role of an orthodontist is crucial, as they can carry out alternative treatments for the same that may fetch better and lasting results for the patient.

Various ethical principles are being violated by MNC'S in their sale of DIY Aligners



,which need to be addressed(2). On the other hand there are certain general dentists ,orthodontists and other specialists of dental profession that suggest and routinely practice with clear aligners for treating malaligned teeth. There is a need to study and assess the ‘why’, ‘how’ and ‘when’ regarding clear aligners used by general dentists and other specialists.

The aim of this survey is to highlight :

- The reasons for DIY Aligners gaining massive popularity among general masses and the ethical principles being violated by MNC’s.
- Knowledge ,attitude and approach of the dental fraternity towards DIY Aligners.

Thus, this survey was designed to assess whether the direct sale of aligners by MNC’S to general population is fruitful or harmful.

## II. METHODOLOGY:

A questionnaire study was conducted among dental professionals in the state of Maharashtra , India. The aim of this study was to assess the knowledge , attitude and approach of dental professionals towards DIY Aligners concept. The participants were selected based upon the following criteria :

- EDUCATION : BDS/MDS/MDS PG Students
- Professionals who were willing to participate at the time of study.

However, dental students (1<sup>st</sup> year to 4<sup>th</sup> year ) were excluded from this survey.

A structured , self-administered ,close – ended questionnaire was pre-tested and validated amongst 20 subjects to assess their knowledge , clarity , responsiveness and individual experience. The questionnaire was prepared on Google form (Google LLC, Mountain View , California USA) to

collect data. The Cronbach alpha value was 0.77,which validates the survey. The questionnaire consisted of knowledge based questions (8), attitude based questions(15) and practice based questions(8) . Demographic details were recorded in the beginning of survey that included the name, age, gender and speciality. A brief introduction was given to the participants before the study. The link for the questionnaire was then circulated among 20 participants for the pilot study via WhatsApp and Email. Following the pilot study , the reliability statistics were calculated.

The link was ,again distributed among the study population via WhatsApp and Email for the main study.The input parameters for sample size calculation used were :80% power of study , alpha-error 0.05 , effect size 0.7 and degree of freedom as 5. The calculated sample size was 289 using G\*Power software version 3.1.9.2 . (Heinrich Heine university ,Dusseldorf) , the final considered sample size was 300 . The convenient sampling technique was used in this study. Data collected was entered in a spreadsheet (Microsoft Excel 2016).Statistical analysis was done using descriptive statistics.

## III. RESULTS:

The results of this study is Summarisedas:

Table1 gives socio-demographic details of the study participants. A total of 301 individuals participated in the study. Out of 301, 182 were females and 119 were males. Age groups ranging from 20-30 years have shown maximum participation in the study(approx79%). A total of 100 BDS graduates, 84 MDS students and 117 MDS post-graduates of various specialties’ have participated in this study.

Table1: Respondents Demographics

GENDER		FREQUENCY	PERCENTAGE
	FEMALE	182	60.5%
	MALE	119	39.5%
AGE GROUP			
	20-30 yrs		79%
	31-40yrs		14.6%
	Above 40 yrs		6.3%



QUALIFICATION			
	BDS Graduate	100	33.2%
	MDS Student	84	27.9%
	MDS Post Graduate	117	38.9%

Table 2 assesses the knowledge of participants towards the DIY Aligners. Fixed orthodontic treatment has been recommended to patients by approximately 88% of the participants. Around 83.4% of the respondents believe that expense, lack of patient co-operation and the inability to yield good results in certain malocclusions, limits the usage of DIY Aligners. About 87.7% agree to MNCs playing a major role in advertising DIY Aligners. However, 77.4% believe that the major cause for failure of DIY

Aligners is lack of orthodontic guidance. Study indicates that 45.5% feel the major problem faced by patients using DIY Aligners is lack of follow-ups. About 93.7% of the respondents believe, that the chances of relapse in DIY Aligners treatment are more in comparison to professionally guided treatment. Around 81.4% have observed an increase in maltreated cases in DIY Aligner treatment. Approximately 89% believe that Fixed orthodontic treatment has better prospects of fetching desired results.

Table 2: Shows of responses of participants about their knowledge related to DIY Aligners

KNOWLEDGE BASED	RESPONSES	FREQUENCY(n)	PERCENTAGE (%)
1. What is your choice of treatment for mal-aligned teeth?	Aligners	18	6
	Braces-metal	139	46.2
	Braces-ceramic	126	41.8
	Lingual Orthodontics	18	6
2. What limits the usage of DIY aligners	Expense	11	3.6
	Patient Co-operation/Comfort	13	4.3
	Ineffective in certain malocclusions	26	8.6
	All of the above	251	83.4
3. Who according to you have advertised DIY more?	MNCs	864	87.7
	General Dentists	7	2.3
	Orthodontists	8	2.6
	Others (Friends/Family)	22	7.3
4. What causes failure in aligner treatment provided via MNCs?	Lack of Knowledge	31	10.3
	Lack of Orthodontic Guidance	233	77.4
	Poor customer service	16	5.3
	Failure in patient compliance	21	7
5. Which ethical principle are MNC's violating by selling DIY aligners without orthodontic	To do no harm	7	2.3
	Autonomy	6	1.9
	Truthfulness	8	2.6



guidance?	All of the above	280	93
6. What are the common problems patients face when they directly purchase aligners from MNCs?	Failure of treatment	139	42.6
	Poor customer service	20	6.6
	No follow-ups	137	45.5
	None of the above	5	1.6
7. Which of the following treatments have more chances of relapse?	Aligners via MNCs	282	93.7
	Aligners via general dentists	12	3.9
	Aligners via orthodontists	2	0.6
	None of the above	5	1.6
8. How has the sale of aligners via MNCs affected orthodontists?	Decrease in patient flow	19	6.3
	Increased awareness regarding orthodontics	28	9.3
	Increased maltreated cases	245	81.4
	None of the above	9	2.9
9. Which of the following has good prospects of fetching better results?	Aligners	7	2.3
	Braces - metal	153	50.8
	Braces - ceramic	119	39.5
	Lingual orthodontics	22	7.3
	Braces - ceramic	119	39.5
	Lingual orthodontics	22	7.3

Table 3 assesses the attitude of participants towards the subject of study. TMJ examination has been considered significant for treatment planning by around 86% of the participants. Around 89.4% believe unmonitored orthodontic treatment can

cause irreversible changes to your facial profile. Approximately 77.7% strongly agree to the sale of DIY Aligners being unethical and outside the realms of professional accountability.

Table 3: Shows the attitude of participants towards DIY Aligners

ATTITUDE BASED	RESPONSES	FREQUENCY (n)	PERCENTAGE (%)
1. TMJ examination has great significance in prognosis of the treatment.	Strongly Agree	259	86
	Agree	39	13
	Neutral	1	0.3
	Disagree	1	0.3
	Strongly Disagree	1	0.3



2.Unmonitored orthodontic treatment can cause irreversible damage to your teeth and jaws.	Strongly Agree	269	89.4
	Agree	28	9.3
	Neutral	3	0.9
	Disagree	0	0
	Strongly Disagree	1	0.3
3.In DIY aligners, your provider and their treatment is out of the realms of professional accountability.	Strongly Agree	234	77.7
	Agree	50	16.6
	Neutral	15	5
	Disagree	2	0.6
	Strongly Disagree	0	0

Table4 assesses the participants practice routine in their workspace. Information regarding relapse and retention plans have been provided by around 90.4% of the participants. Around 47.2% have observed maltreated cases of DIY Aligner in

their day to day practice. Scanning procedures are carried under expert's guidance by around 73.4% of respondents. Patients are attended regarding any problems or complaints associated with the treatment by approximately 90%.

Table 4: Shows the participants practice routine in their workspace.

PRACTICE BASED	RESPONSES	FREQUENCY (n)	PERCENTAGE (%)
1.Do you inform the patients about relapse and need for retention plan?	Always	272	90.4
	Often	28	9.3
	Rarely	1	0.3
	Never	0	0
2.Have you ever treated/observed failed cases of DIY aligners?	Always	108	35.9
	Often	142	47.2
	Rarely	35	11.6
	Never	16	5.3
3.Do you carry out scanning procedures under an expert's	Always	221	73.4



guidance?	Often	69	22.9
	Rarely	7	2.3
	Never	4	1.3
4.Do you attend to patient's complaints regarding their treatment?	Always	271	90
	Often	25	8.3
	Rarely	3	0.9
	Never	2	0.6

#### IV. DISCUSSION:

Orthodontics is a branch of dental speciality established by Dr. Edward H. Angle in 1900. Orthodontics are specialists that acquire additional training apart from their basic dental degree in treating irregularities of teeth, jaws and face. Several problems are encountered by the profession, including general dentists providing orthodontic care and now to top that various companies are selling clear aligners without providing the essential orthodontic guidance needed to treat complex malocclusions. The American Association of Orthodontics have also taken various measures to caution orthodontics which in turn have lead them to warn and inform their patients the several demerits of using DIY Aligners. This current study has attempted to identify the limits and disadvantages of using DIY Aligners and the importance of orthodontic guidance in treating malaligned cases. Teleorthodontics has been a major setback in terms of healthcare and to the profession of dentistry.

The findings of this research with respect to limitations and disadvantages of using DIY aligners are consistent with previous studies in the field. The popularization of DIY aligners are positively overwhelming due to comfort, time effectiveness and for esthetic reasons (86.7%), which is consistent with the studies conducted by Oslon.<sup>[1]</sup> According to a study conducted by Anna Wexler on participants (white, female millennial 23-38yrs old) who have undergone aligner treatment to correct crowding. Around one-half of the population considered consulting a dentist before undergoing any further treatment, which led to dentists recommending in- office treatment. However 87.5% if the respondents continued with

DIY Aligners and around 6.6% of them had to visit an orthodontist due to severity of side effects.<sup>[23]</sup>

Also the COVID-19 pandemic lockdown restrictions and orthodontic and dental offices temporarily closed worldwide, patients may have been more likely to seek DIY Aligner solution when they were restricted to the safety of their home. A majority of malocclusions require additional procedures that include IPR, elastics, extractions, temporary anchorage devices for treating malaligned cases. Whereas, MNCs involved in the sale of DIY Aligners do not provide these additional services. During a cross-sectional population based survey conducted in the United States of America, more than 83% of the participants have considered pursuing orthodontic treatment to some extent. 23% reported that they would highly likely choose Direct-to-consumer orthodontic products. The majority of participants reported convenience to be the greatest benefit of Direct-to-consumer Orthodontics, followed by cost. The majority of responses seemed to favor Direct-to-consumer Orthodontics. Around 47% reported that the coronavirus disease 2019 pandemic did not affect their preference, whereas 26.6% reported to be more likely to pursue Direct-to- consumer orthodontics because of the pandemic.<sup>[22]</sup>

The COVID-19 pandemic made it nearly impossible for the population to have access to dental clinics which in turn led to people depending on social media to find solutions to their various healthcare problems. In accordance with studies conducted by Collins, the videos uploaded on various social media platforms regarding information related to DIY aligners are of poor quality, misleading and are not recommended to patients as a reliable source of information.<sup>[4]</sup> M J Meade evaluated 21 websites of direct-to-consumer



orthodontic aligner providers. Few websites referred to the need for pre-treatment dental health (38.1%) and indefinite post-treatment retention (23.8%). Most websites (95.2%) were categorized as either 'poor' or 'very poor' according to their DISCERN scores (an instrument designed to provide users with reliable way to measure the quality of written health information). The readability scores indicated 'difficult to read' content.<sup>[16]</sup>

The findings of this study indicate fixed orthodontic treatment to be the choice for correcting malaligned teeth. In accordance to a study conducted by Riley, the 60 videos included were viewed 34.4 million times by internet users. Braces videos had significantly more likes, comments, and a higher viewer interaction score than the In-office Aligners and Direct-to-consumer aligner videos. In-office aligner videos had a higher median information completeness score than braces and Direct-to-consumer aligner videos. Of the 5149 video comments with polarity, 53.6% were positive, and 46.4% were negative ( $P < 0.0001$ ). There was no significant association between the treatment modality and positive or negative comments ( $P = 0.5679$ ).<sup>[24]</sup> Orthodontic specialists are trained to give comprehensive care for a range of complex malocclusions, whereas DIY Aligners focus only on aligning and levelling of teeth. However, individuals with minor complications have sought orthodontic treatment compared to individuals with complex complications according to Shaw WC.<sup>[5]</sup>

## V. CONCLUSION:

There are varieties of treatment modalities which are available to the general population. The treatment provided should grant the patient maximum care and high-grade quality service and hence it is required to educate potential patients on the value of pursuing treatment with highly qualified orthodontic specialists. DIY aligners are preferred over orthodontic treatment as they are known for being cost-effective and less time consuming while conventional orthodontics offer quality despite its other drawbacks. The videos' dependability and quality while providing information regarding the use of DIY aligners are often subpar and unreliable due to a lack of scientific and factual data.

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